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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,082	12/12/2003	Cole H. Chen	A01P1051US02	3271

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PACESETTER, INC.
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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/736,082	CHEN ET AL.
	Examiner	Art Unit
	Kristen Mullen	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/12/03 (app. filing)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15 and 35-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15,35-44,46 and 47* is/are rejected.

7)☒ Claim(s) *45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The specification contains a reference to the parent application by its application number. This application has since been abandoned. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents or been abandoned.

Claim Objections

2. Claims 13 and 42 are objected to because of the following informalities: "reinforcing silicone" should be changed to --reinforcing silica-- to agree with the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9, 35-37, 39, 43-44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil Jr. et al. (4,819,662).

Regarding claim 9, Heil shows a method comprising: providing an endocardial lead which contains a drug-eluting means for dispensing a drug and has a distal tip; combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a mixture thereof, applying the mixture to the distal tip of the lead; and allowing the mixture to cure in place in the lead (Fig. 1; Col. 4, line 45 - Col. 5, line 3).

With respect to claim 35, Heil shows a method comprising: combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a mixture thereof, dispensing the mixture to a distal portion of the endocardial lead; and allowing the mixture to cure at the distal portion of the endocardial lead (Fig. 1; Col. 4, line 45 - Col. 5, line 3).

Regarding claim 36, Heil shows applying the mixture to a distal portion comprises applying the mixture within a chamber (36) of the endocardial lead (Fig. 1).

With respect to claims 37 and 46, Heil shows the endocardial lead is a passive lead (via tines 26).

Regarding claim 39, Heil shows the the inflammation-reducing drug is a steroid (dexamethasone sodium phosphate).

With respect to claim 43, Heil shows a method comprising: combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a pourable (viscous or malleable state) mixture thereof, dispensing the pourable mixture into a distal portion of the endocardial lead; and curing the pourable mixture in the distal portion of the endocardial lead (Fig. 1; Col. 4, line 45 - Col. 5, line 3).

Regarding claim 44, Heil shows providing a chamber (36) at the distal portion of the endocardial lead; wherein the dispensing the pourable mixture comprises dispensing the mixture within the chamber (Fig. 1; Col. 4, line 45 - Col. 5, line 3).

5. Claims 9, 35-36, 38-39, 43-44, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil Jr. et al. (4,819,661).

Regarding claim 9, Heil shows a method comprising: providing an endocardial lead which contains a drug-eluting means for dispensing a drug and has a distal tip; combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a mixture thereof, applying the mixture to the distal tip of the lead; and allowing the mixture to cure in place in the lead (Fig. 4; Col. 4, lines 14-18; Col. 4, line 64 - Col. 5, line 4).

With respect to claim 35, Heil shows a method comprising: combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a mixture thereof, dispensing the mixture to a distal portion of the endocardial lead; and allowing the mixture to cure at the distal portion of the endocardial lead (Fig. 4; Col. 4, lines 14-18; Col. 4, line 64 - Col. 5, line 4).

Regarding claim 36, Heil shows applying the mixture to a distal portion comprises applying the mixture within a chamber (54) of the endocardial lead (Fig. 4).

With respect to claims 38 and 47, Heil shows the endocardial lead is an active fixation lead (via helix 20).

Regarding claim 39, Heil shows the inflammation-reducing drug is a steroid (dexamethasone sodium phosphate).

With respect to claim 43, Heil shows a method comprising: combining an inflammation-reducing drug (dexamethasone sodium phosphate) with a drug carrying silicone elastomer to form a pourable (viscous or malleable state) mixture thereof, dispensing the pourable mixture into a distal portion of the endocardial lead; and curing the pourable mixture in the distal portion of the endocardial lead (Fig. 4; Col. 4, lines 14-18; Col. 4, line 64 - Col. 5, line 4).

Regarding claim 44, Heil shows providing a chamber (54) at the distal portion of the endocardial lead; wherein the dispensing the pourable mixture comprises dispensing the mixture within the chamber (Fig. 4; Col. 4, lines 14-18; Col. 4, line 64 - Col. 5, line 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 10-12, 14 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil Jr. et al. (4,819,662) as applied to claims 9 and 35 above and further in view of Ding et al. (5,837,313).

Regarding claims 10 and 40, Heil is as explained before. Heil further shows applying the mixture that has been combined (i.e. third mixture) into the distal tip of the lead and curing the mixture applied at the tip. Although Heil fails to show the specific steps of combining an inflammation reducing drug and a drug carrying silicone elastomer to form a mixture and curing at a predetermined temperature, attention is directed to Ding who shows a method of combining an inflammation-reducing drug with a drug carrying silicone elastomer for the purpose of applying the mixture in a fluent state to a medical device and subsequently curing the mixture on the medical device at a predetermined temperature. The combining method disclosed by Ding comprises the steps of combining a wetting fluid component (Tetrahydrofuran (THF)) and the inflammation- reducing drug (dexamethasone free alcohol or acetate) to form a first mixture; combining the first mixture and a base component (silicone) to form a second mixture (silicone,

dexamethasone and THF), and combining the second mixture and a curing component (crosslinker) to form a third mixture and curing the third mixture at a predetermined temperature (Col. 7, lines 8-29, Col. 8, lines 21-36). It would have been obvious to one with ordinary skill in the art at the time the invention was made to include the specific combining steps of Ding for combining the inflammation reducing drug with the drug carrying silicone in the method of Heil in order to achieve a mixture that could be applied in a fluent state to the medical device and to be subsequently cured on the medical device at the predetermined temperature.

Regarding claims 11 and 41, Ding shows the curing step comprises the step of elevating the temperature to the predetermined value being in the range of about 40 degrees C to 75 degrees C (50^0 C RTV) (Col. 8, line 25-29).

With respect to claim 12, Ding and Heil both show that the inflammation-reducing drug is a steroid (dexamethasone).

Regarding claim 14, Ding shows the curing component is a platinum catalyst (Col. 7, lines 3-5).

8. Claims 13 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil Jr. et al. (4,819,662) in view of Ding et al. (5,837,313) as applied to claims 10 and 40 above and further in view of Sano et al. (6,756,048). Heil and Ding are as explained before. Ding also shows that he curing component is a platinum catalyst (Col. 7, lines 3-5). Although Heil and Ding fail to show the base component comprises reinforcing silica in addition to the dimethylsiloxane polymer (polydimethylsiloxane) attention is directed to Sano who teaches that silica is added to drug impregnated silicone for enhancing the physical strength and is known to influence the release rate of drugs (Col. 1, lines 62-65). Therefore, it would have been obvious

to one with ordinary skill in the art at the time the invention was made to modify the method of Heil and Ding to include silica in the base component as Sano teaches in order to enhance the physical strength of the base component and influence the drug release rate.

9. Claims 13 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil Jr. et al. (4,819,662) in view of Ding et al. (5,837,313) as applied to claims 10 and 40 above Heil and Ding are as explained before. Ding teaches curing temperatures of 50^0 C, 90^0C or even as high as 150^0C. Ding also teaches that cure time and temperature may vary with particular silicones, crosslinkers and biologically active species (Col. 8 lines 24-27; Col. 4 lines 8-20). It has been recognized by our reviewing courts that differences in temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). Absent evidence that a cure temperature of 55^0 C is critical, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Heil and Ding to optimize the predetermined curing temperature at 55^0 C in view of the prior art teachings of curing temperatures of 50^0 C, 90^0C or even as high as 150^0C.

Allowable Subject Matter

10. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

kdm